

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



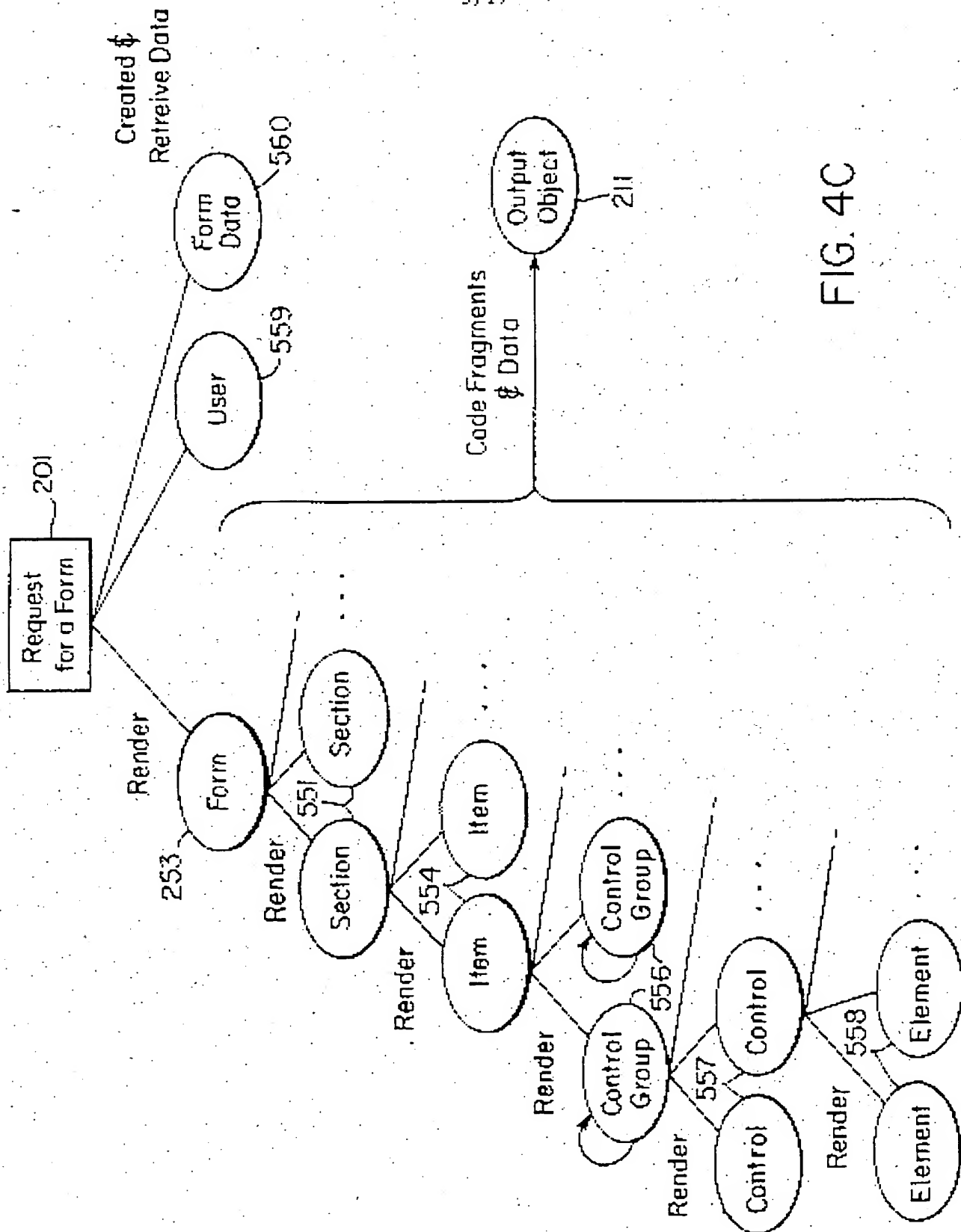


FIG. 4C

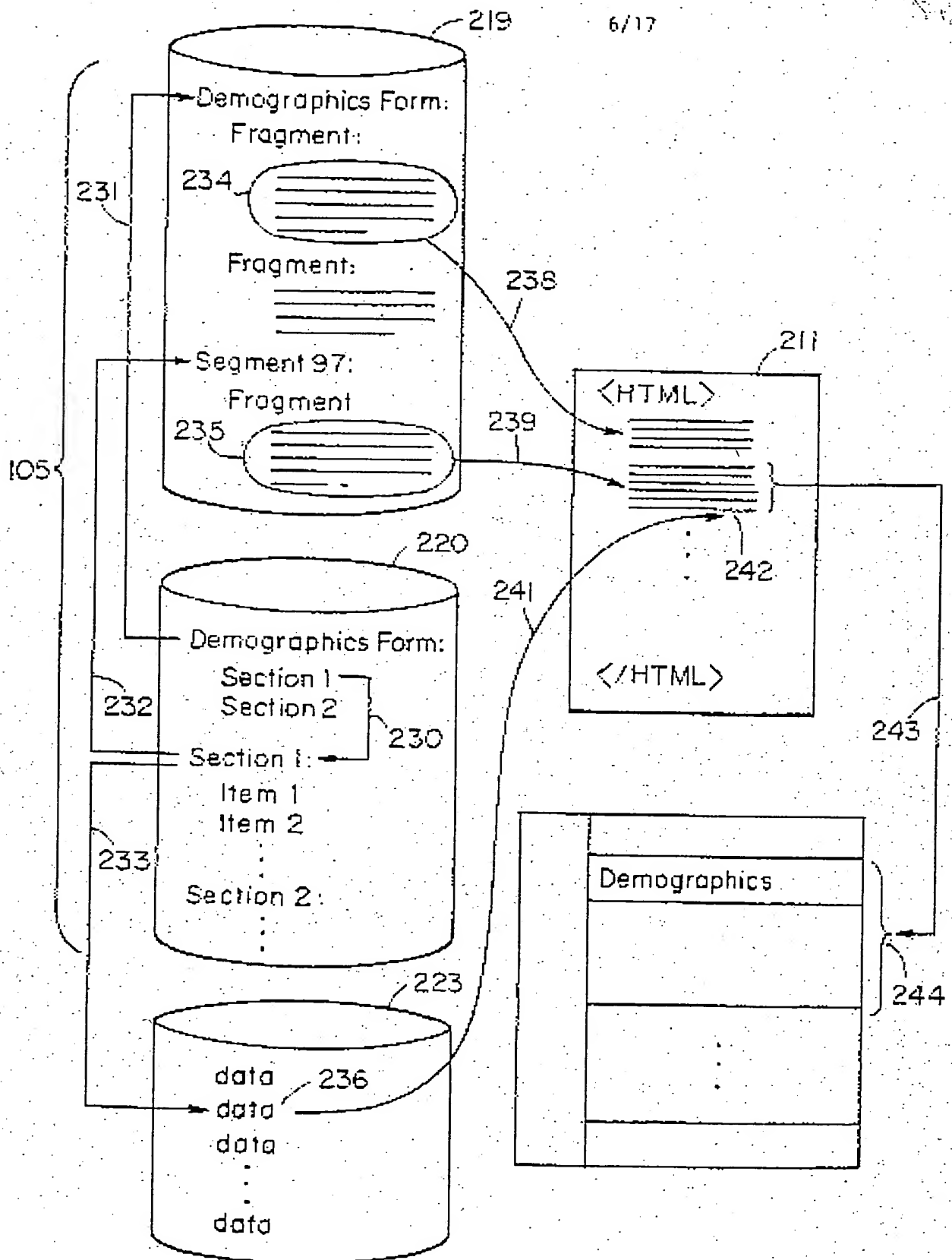


FIG. 4D

275      7/17      251B

John E. Raymond  
Laboratory Assistant

Home Help Logout  
Enrollment  
Visits  
Queries  
Status  
Documents  
Signatures  
Monitor

Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8  
IF DEM HH ES PE VS/EP ECG/EXR LAB CM

Demographics      Ready for SDV      Patient: JPK      Patient No: CI-DOV

Demographics

1. Gender      Female

2. Date of Birth      Feb 19, 1954

3. Race/Ethnic Origin      Black

4. Height      66 in

5. Weight      145 lb

6. Frame      Medium

Calculated weight variance from avg.      — % Above/Below

Smoking History

7. Has patient ever smoked?      No  
*You indicated that the patient smokes cigarettes in item 9. Please check that as if the patient smokes or "Has the patient ever smoked?"*

8. If the patient has ever smoked, has the patient quit smoking?      No

9. If the patient currently smokes, the patient smokes:      Cigarettes

10. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:      1

Next Reverse Exit

251A

JPH/CI/Week 4 Dem  
JPH/CI/Week 4 ECG  
JPH/CI/Week 4 ECG  
JPH/CI/Week 4 ECG  
JPH/CI/Week 4 ECG

FIG. 5

291

# PHASE FORWARD

## InForm™

Please enter your name and password

Account name      jsmith      293

Password      \_\_\_\_\_      295

Log in      297

FIG. 6

8/17

Jennifer Smith, RN  
Clinical Research  
Coordinator

Home Help Logout

Enrollment

Visits

Queries

Status

Documents

JPH/OIWk-4 Dem  
JPH/QI-Wk-4 ECG  
JPH/QI-T&E Sched  
Site OI GRBs

## PHASE 3

### PF-105 Clinical Drug Trial

#### Study News

When Alvin's blood pressure was 180/110 mm Hg, Dr. Stoyol, P.A. Harner, Mechanisms of Antihypertensives treatment was given. The treatment was successful.

#### Alerts

Indicate when the patient's blood pressure was 180/110 mm Hg. The treatment was successful.

#### Enrollment

When the patient's blood pressure was 180/110 mm Hg, the treatment was successful.

January's Top Enrolling Sites

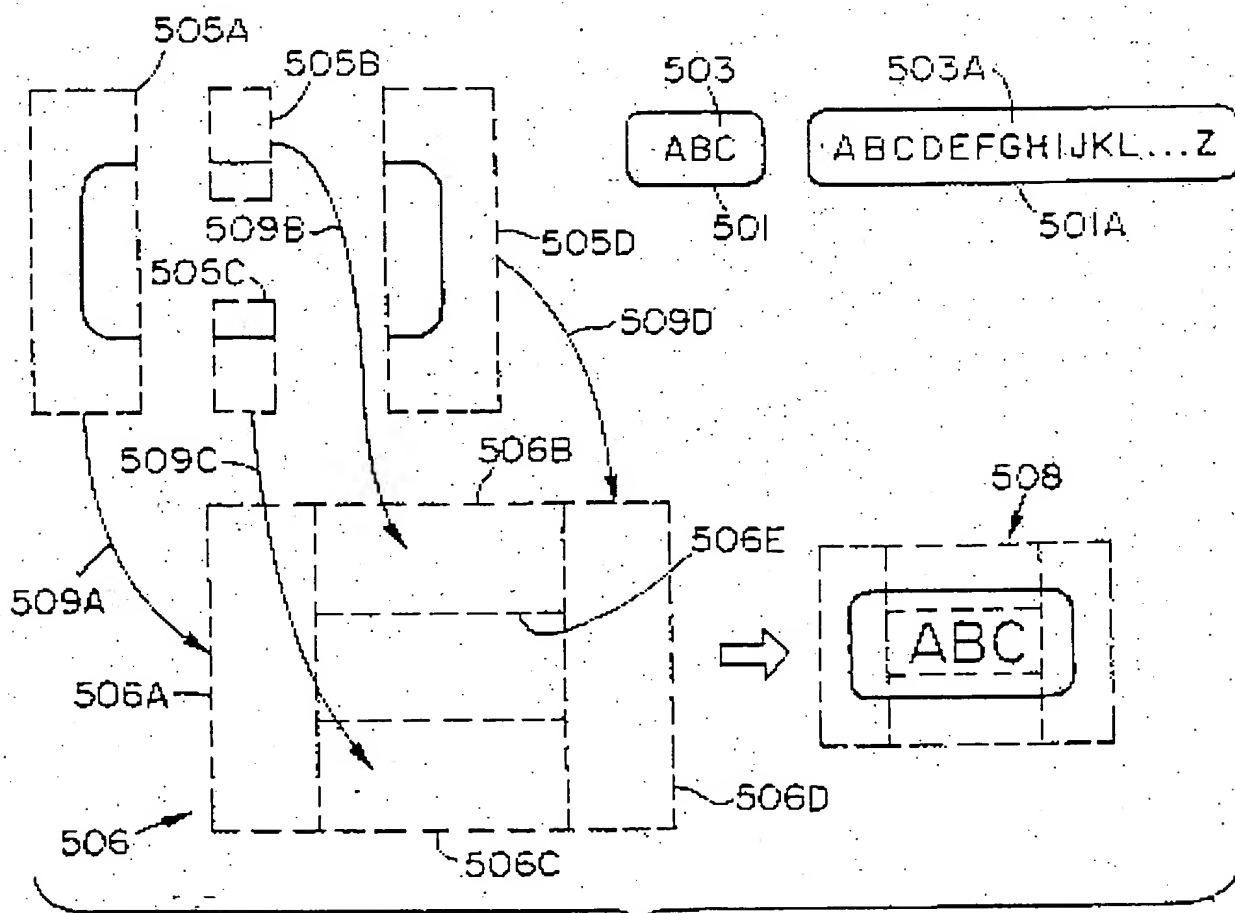
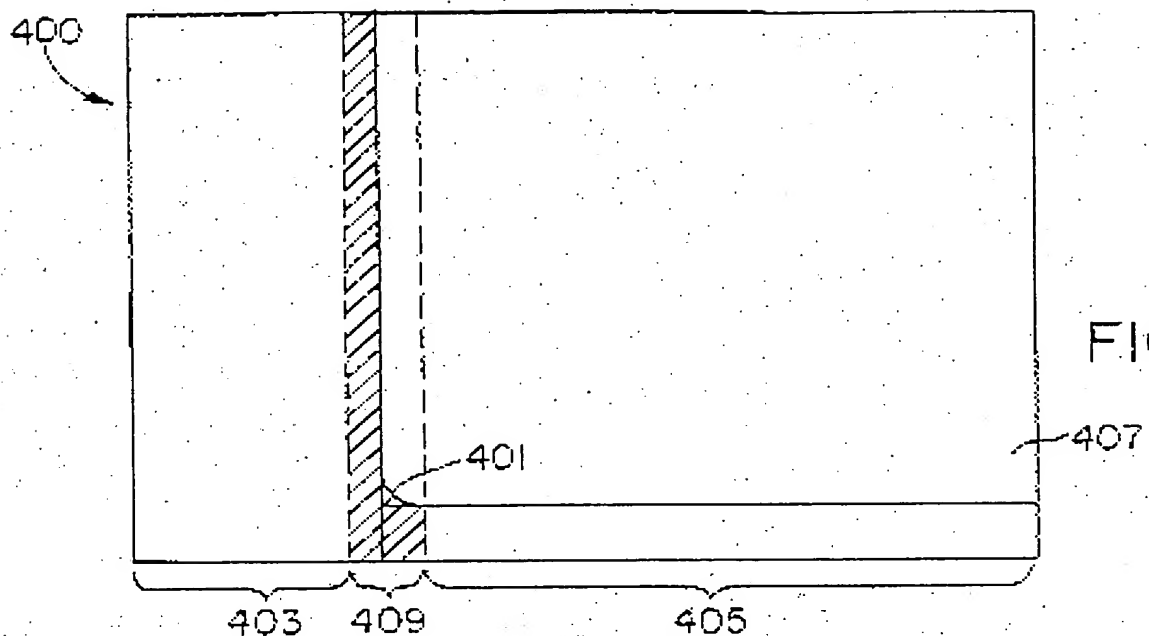
#### Study Data Process

CRBs to Complete

Patients		
Alvin Smith	180/110 mm Hg	
Dr. Stoyol	180/110 mm Hg	

Patient No.  01-001  Week-4

FIG. 7



10/17

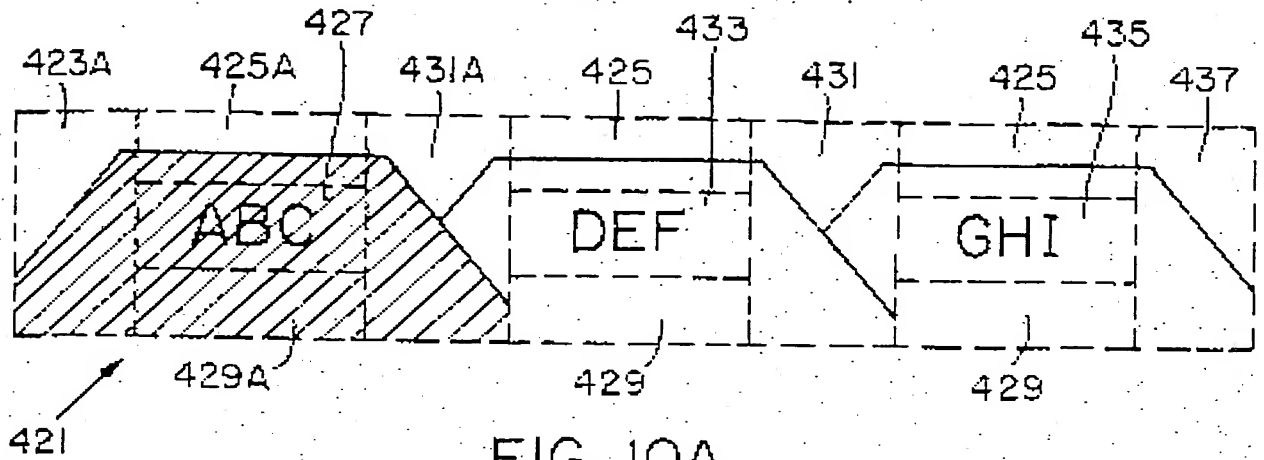


FIG. 10A

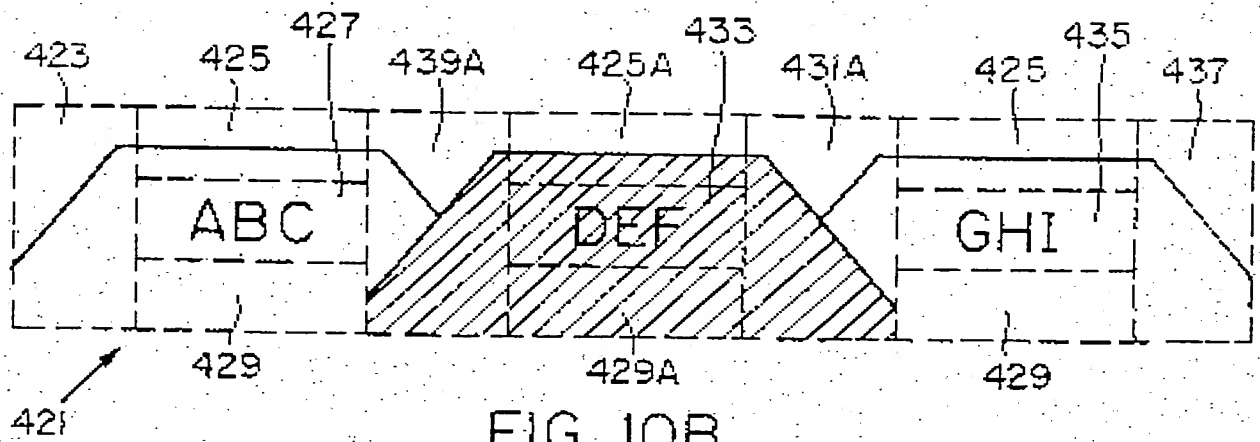


FIG. 10B

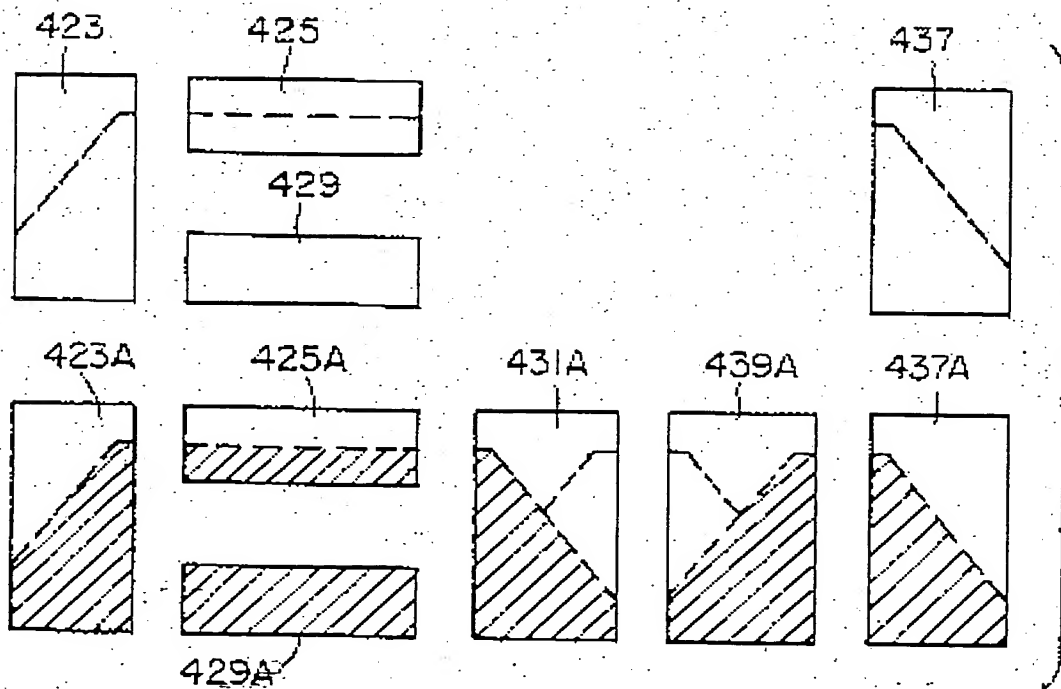


FIG. 10C



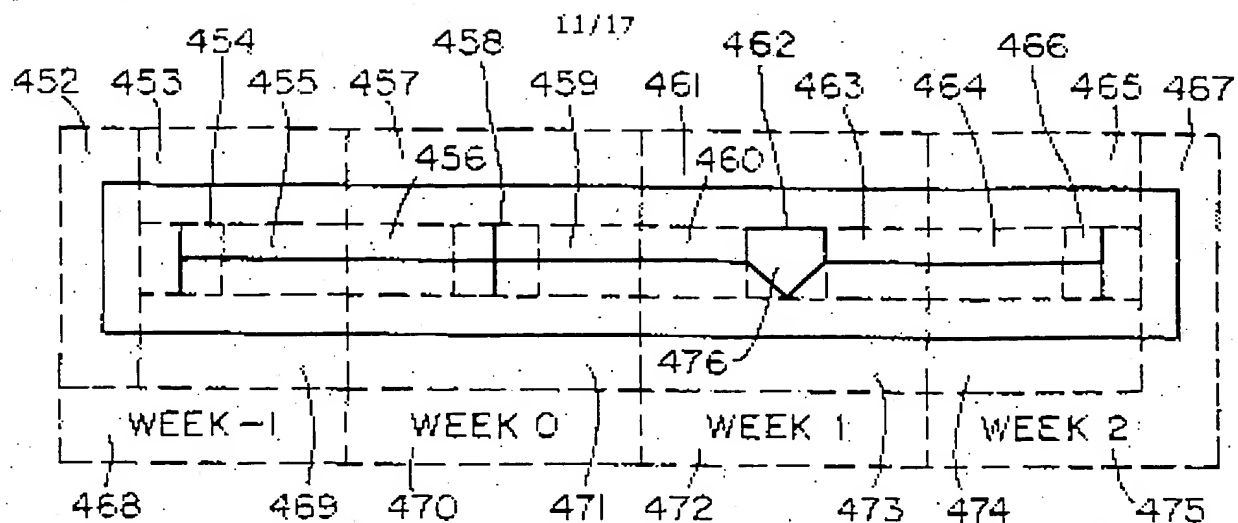


FIG. 11A

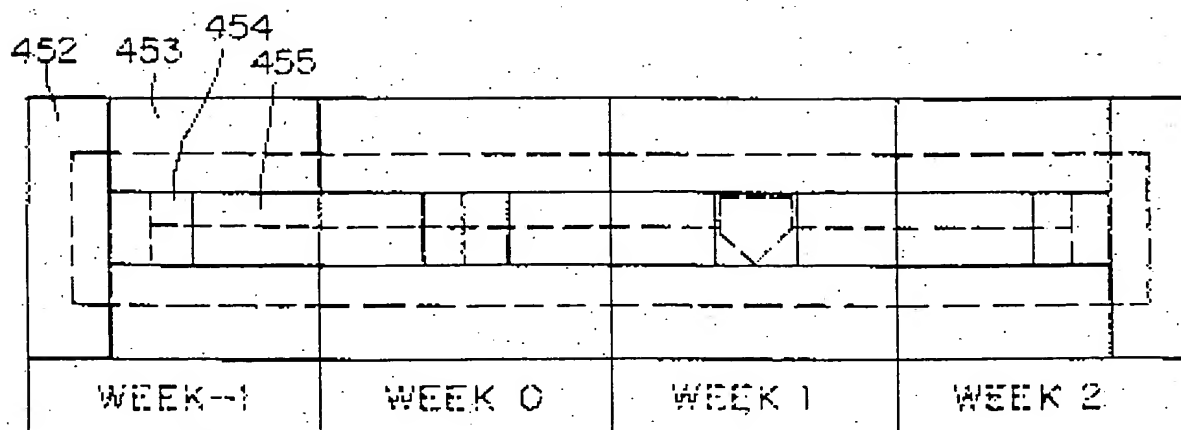


FIG. 11B

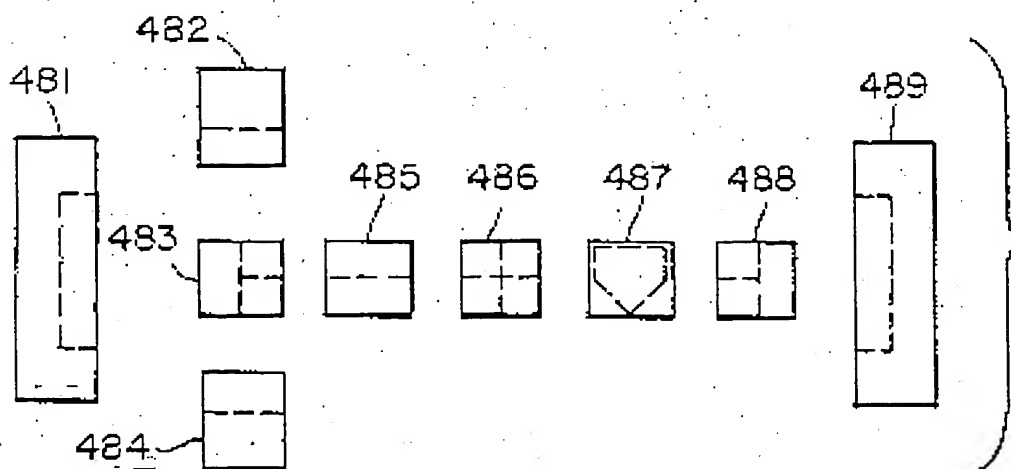


FIG. 11C

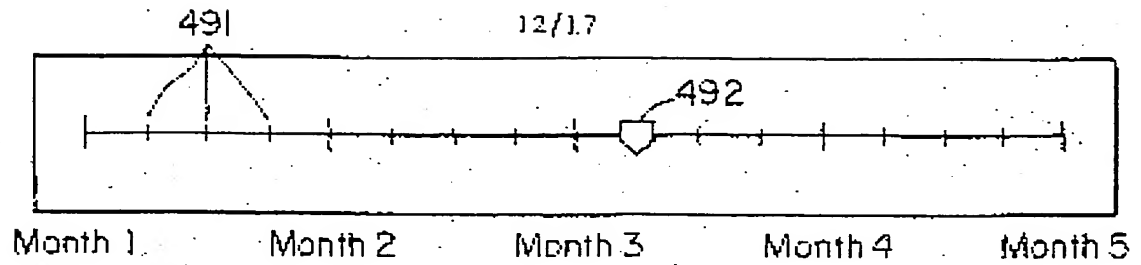


FIG. 11D

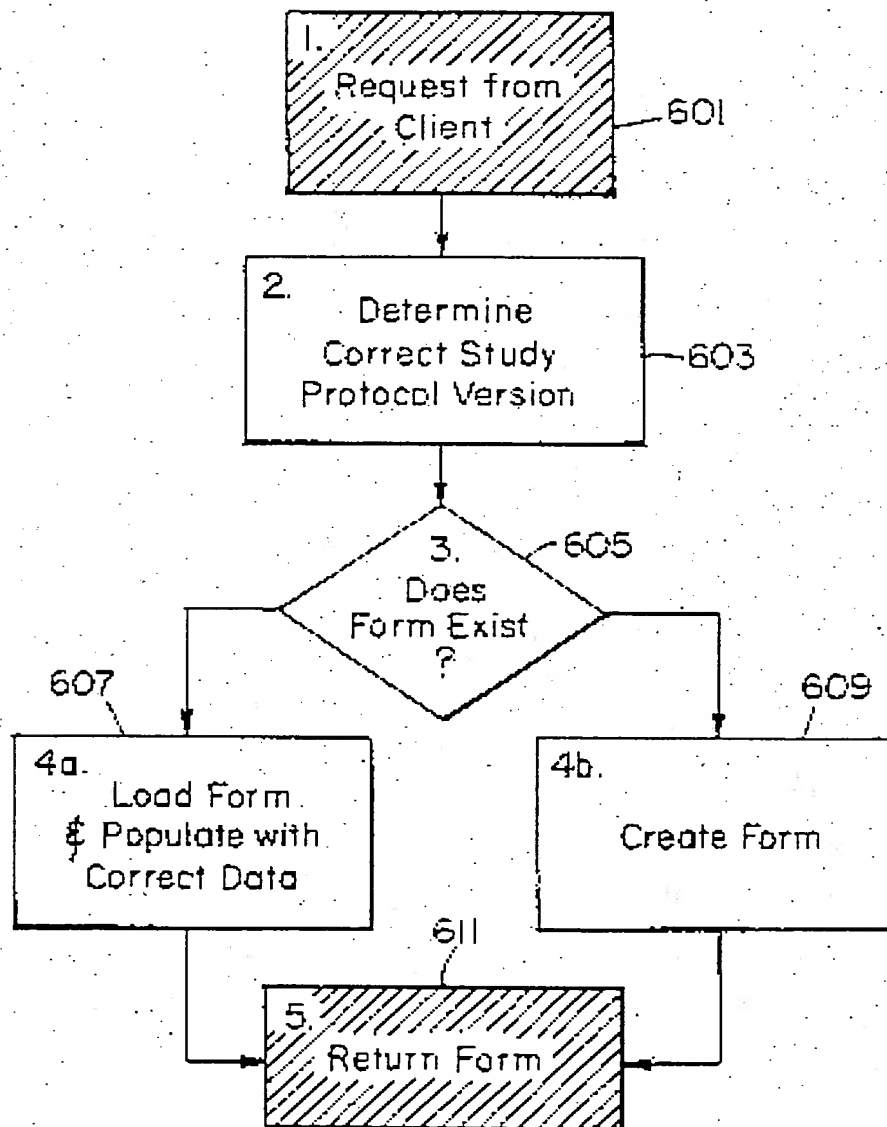


FIG. 12A

PROTOCOL VERSION 1

PROTOCOL VERSION 2

[illegible]

FIG. 12C

15/17

Help Link  
BO1

Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8

IF DEM HH SS PE VS/BP ECG/CXR LAB CM

Demographics Ready for SDV Patient: JPK Patient No: DI-COI

Demographics

1 Gender ☐ Male ☒ Female

2 Date of Birth Feb 19 1984

3 Race/Ethnic Origin ☒ Black ☐ Other (Specify)

4 Height: 66 ☒ In ☐ Cm

5 Weight: 145 ☒ lb ☐ kg

6 Frame: Medium

Calculated weight variance from avg. % Above/Below

Smoking History

7 Has patient ever smoked? ☒ Yes ☐ No ☐ Not Done

8 If the patient has ever smoked, has the patient quit smoking? ☒ Yes ☐ No ☐ Not Done

9 If the patient currently smokes, the patient smokes: ☒ Cigarettes ☐ Pipes ☐ Cigars ☐ Not Done

10 If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: 1 ☐ Unknown ☐ Not Done

Submit Cancel

FIG. 13A

Context Sensitive  
Help BO4

Help Window  
BO3

Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8

IF DEM HH SS PE VS/BP ECG/CXR LAB CM

Demographics Ready for SDV Patient: JPK Patient No: DI-COI

Demographics

Item 4 Height

- Height must be measured
- Measure height with shoes off
- Report height in either inches or centimeters. (The entry will be converted to the desired units for report purposes.)

Item 5 Weight

- How should weight be measured?
- Enter as height in the current data table.

Item 6 Frame

- How should frame be measured?
- Enter as height in the current data table.

Smoking History

9 If the patient currently smokes, the patient smokes: ☒ Cigarettes ☐ Pipes ☐ Cigars ☐ Not Done

10 If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: 1 ☐ Unknown ☐ Not Done

Submit Cancel

FIG. 13B

Help Button  
807

16/17

**Jennifer Smith, RN**  
Clinical Research Coordinator

Home Help Logout

Enrollment

Visits

Queries

Status

Documents

JPH/ChWk-4 Dem  
JPH/ChWk-4 ECG  
JPH/ChWk-4 ECG  
Site: GRBS

Week 4 Week 2 Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8

IF DEM HH SS PE VS/BP ECG/CXR LAB CM

Demographics ☒ Ready for SDV Patient: JPK Patient No: 01-001

Demographics

1. Gender: ☐ Male ☒ Female

2. Date of Birth: Feb 19 1954

3. Race/Ethnic Origin: ☐ Black ☐ Other: [specify]

4. Height: 65 in 5cm

5. Weight: 132 lb 6kg

6. Height: [specify]

7. Calculated weight: ☐ Above/Below

Smoking History

1. Has patient ever smoked? ☐ Yes ☒ No ☐ Other ☐ Not Done

2. If the patient has ever smoked, how many cigarettes per day?  [specify] ☐ Unknown ☐ Not Done

3. If the patient currently smokes, how many cigarettes per day?  [specify] ☐ Unknown ☐ Not Done

4. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:  [specify] ☐ Unknown ☐ Not Done

Submit Cancel

FIG. 13C

810

811

Help Window  
809

**Jennifer Smith, RN**  
Clinical Research Coordinator

Home Help Logout

Enrollment

Visits

Queries

Status

Documents

JPH/ChWk-4 Dem  
JPH/ChWk-4 ECG  
JPH/ChWk-4 ECG  
Site: GRBS

Week 4 Week 2 Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8

IF DEM HH SS PE VS/BP ECG/CXR LAB CM

Demographics ☒ Ready for SDV Patient: JPK Patient No: 01-001

Demographics

Phase Forward Help-Microsoft Internet Explorer

Contents Index

Welcome to Clinical Trial Information Environment

Basics

Introducing CTE

Navigating

Managing patient data

Monitoring

Protocols Study Guide Help Investigator Brochure Close

10. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:  [specify] ☐ Unknown ☐ Not Done

Submit Cancel

805

FIG. 13D

811

17/17

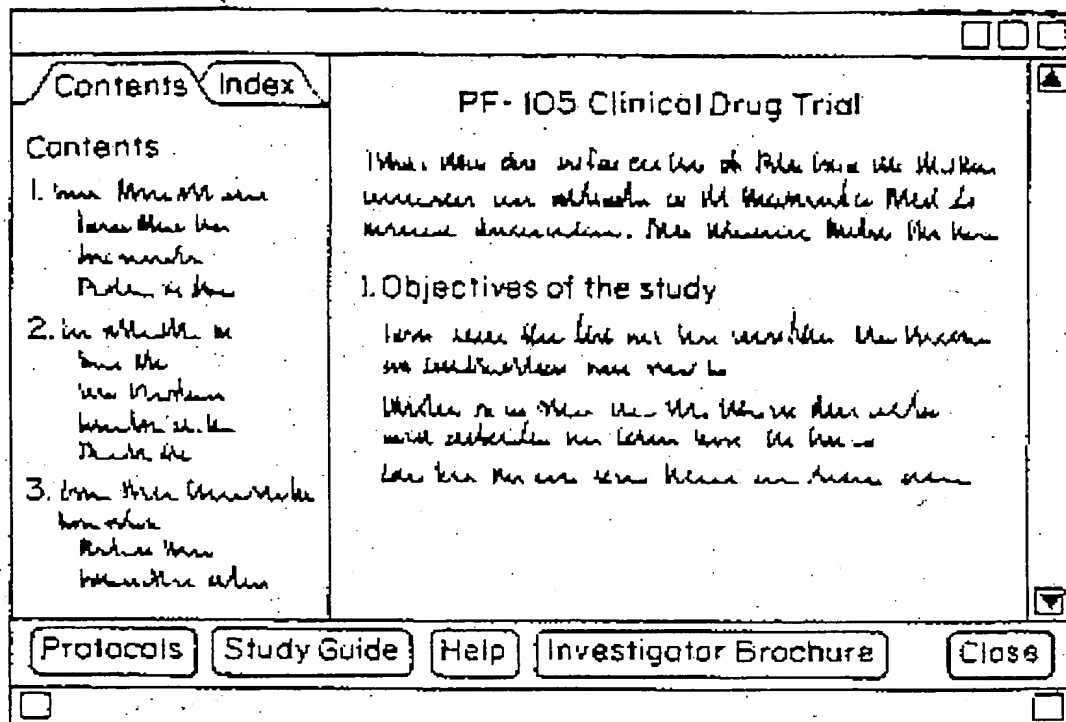


FIG. 13E

812

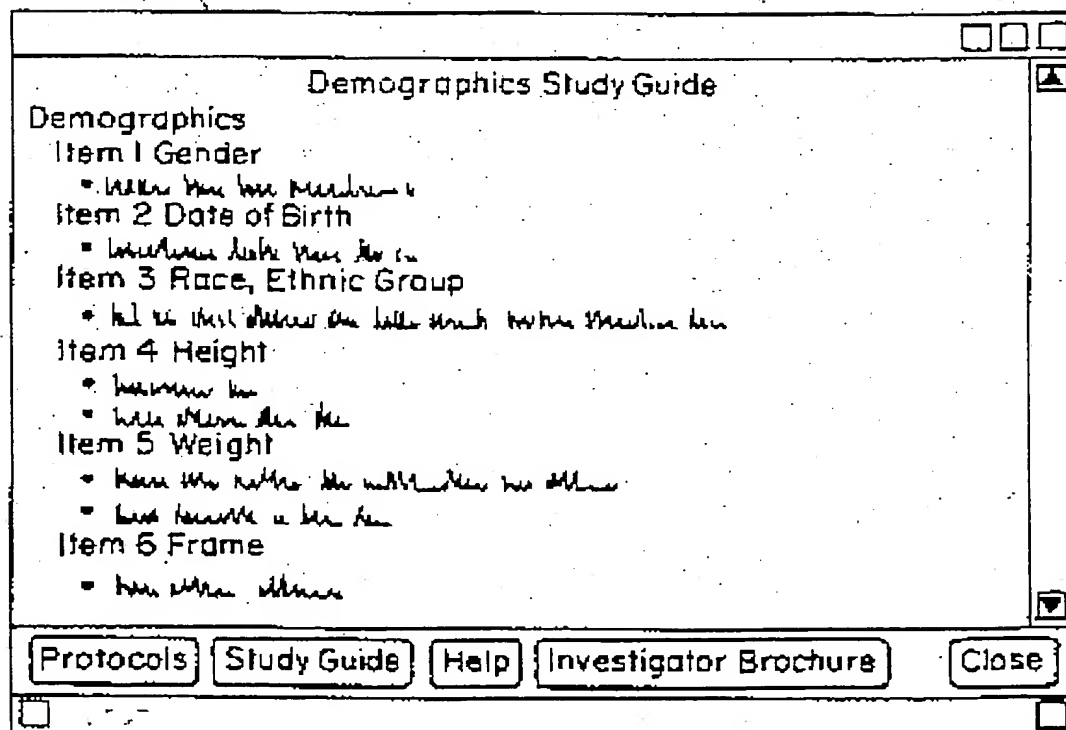


FIG. 13F

3  
C

10





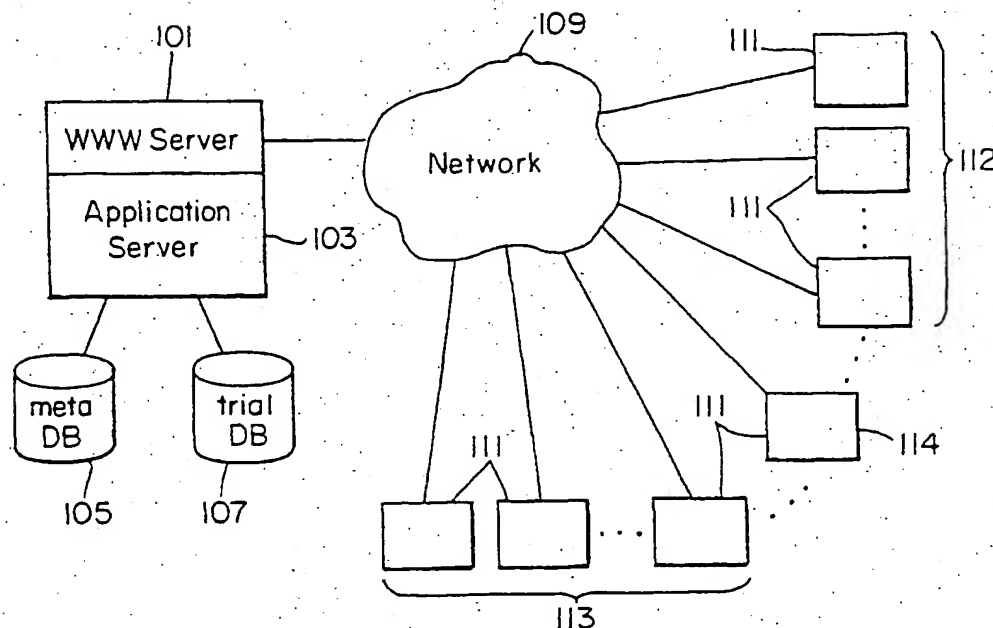
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>G06F 19/00, 9/44</b>		A3	(11) International Publication Number: <b>WO 99/63473</b>
			(43) International Publication Date: 9 December 1999 (09.12.99)
(21) International Application Number: PCT/US99/12406		(81) Designated States: DE, GB, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 3 June 1999 (03.06.99)			
(30) Priority Data: 09/092,441 5 June 1998 (05.06.98) US		Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.	
(71) Applicant: PHASE FORWARD INC. [US/US]; 51 Winchester Street, Newton, MA 02461 (US).		(88) Date of publication of the international search report: 27 January 2000 (27.01.00)	
(72) Inventors: BLEICHER, Paul, A.; 174 Mt. Vernon Street, Newton, MA 02165 (US). STAMOS, Nicholas; 22 Jeannette Avenue, Belmont, MA 02478 (US). KLOFFT, Jeffrey, P.; 33 Hamilton Circle, Marlborough, MA 01752 (US). DALE, Richard, M.; 117 Russell Street, Newton, MA 02165 (US).			
(74) Agents: SMITH, James, M. et al.; Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Drive, Lexington, MA 02421 (US).			

(54) Title: CLINICAL TRIAL DATA MANAGEMENT SYSTEM AND METHOD

## (57) Abstract

A system and method for managing clinical trial data includes dynamically generating, at a server, a data entry form to be displayed at a client. The data entry form is generated dynamically in a SGML-derived language. Control elements within the form comprise images which are used to construct the control elements and larger controls. The form is generated from a protocol database and a context received from the client, is populated from the data database, and is published to the client. Templates based on the protocol database comprise several frames including intermediate frames for displaying frame borders which are non-horizontal and non-vertical. If the trial protocol changes during a trial, the generated form is based on the protocol version active at the time data was entered into the form. Inadvertent use of the application is discouraged requiring an authentication procedure and displaying a picture of the authenticated user. Furthermore, help is provided by creating a link between the text of each question and information about the question. The source of help may be any or all of a protocol document, an investigative brochure, and a study guide. In addition, a user, upon logging in, is presented with a dashboard screen which provides information or links to information such as trial-related news, alerts, statistical information, progress reports and a list of work to be completed.



*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/12406

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 G06F19/00 G06F9/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KIUCHI T ET AL: "Automated generation of a World Wide Web-based data entry and check program for medical applications" COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE, FEB. 1997, ELSEVIER, NETHERLANDS, vol. 52, no. 2, - February 1997 (1997-02) pages 129-138, XP002123139 ISSN: 0169-2607 the whole document — —/—	1-56



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

18 November 1999

Date of mailing of the international search report

03/12/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Fonderson, A

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/12406

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KELLY M A ET AL: "The Internet and randomised controlled trials" INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS, IR, ELSEVIER SCIENTIFIC PUBLISHERS, SHANNON, vol. 47, no. 1-2, - 1997 page 91-99 XP004107516 ISSN: 1386-5056 the whole document	1-56
A	"MULTI-STATE BUTTON MANIPULATION USING A SINGLE GRAPHIC" IBM TECHNICAL DISCLOSURE BULLETIN, US, IBM CORP. NEW YORK, vol. 38, no. 4, page 585-587 XP000516262 ISSN: 0018-8689 the whole document	5, 24, 25, 28-31, 35, 36, 43, 44, 46, 47, 50, 53, 54
A	ANONYMOUS: "Efficient 3D Buttons in Dynamic Hyper Text Markup Language Pages" IBM TECHNICAL DISCLOSURE BULLETIN, vol. 41, no. 1, pages 695-698, XP002123140 New York, US the whole document	5, 24, 25, 28-31, 35, 36, 43, 44, 46, 47, 50, 53, 54
A	GIRGENSOHN A ET AL: "Seamless integration of interactive forms into the Web" COMPUTER NETWORKS AND ISDN SYSTEMS, NL, NORTH HOLLAND PUBLISHING. AMSTERDAM, vol. 29, no. 8-13, page 1531-1542 XP004095347 ISSN: 0169-7552 the whole document	7-17, 42
A	NETSCAPE COMMUNICATIONS CORP.: "NetHelp" NETHELP RELEASE 1.0 SDK DOCUMENTATION, 'Online!' - August 1996 (1996-08) pages 1-14, XP002071214 USA Retrieved from the Internet: <URL: <a href="http://home.netscape.com/eng/help/sdk1/sdksite.htm">http://home.netscape.com/eng/help/sdk1/sdksite.htm</a> > 'retrieved on 1998-07-10! the whole document	7-17, 42